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I hereby certify that this paper (along with any paper referred to as being attached or enclosed) is being deposited with the U.S. Postal Service on the date shown below with sufficient postage as First Class Mail, in an envelope addressed to: MS Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Dated: May 29, 2007

Signature: Action & Market

Docket No.: 27373/40386

(PATENT)

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re **S**atent Application of: 🖔 Eughte B. Chang et al.

Application No.: 10/589,544

Confirmation No.: 6616

Filed: August 16, 2006

Art Unit: 1614

For: ANTI-INFLAMMATORY,

Examiner: Not Yet Assigned

CYTOPROTECTIVE FACTOR DERIVABLE

FROM A PROBIOTIC ORGANISM

## **INFORMATION DISCLOSURE STATEMENT (IDS)**

MS Amendment Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Dear Sir:

Pursuant to 37 CFR 1.56, 1.97 and 1.98, the attention of the Patent and Trademark Office is hereby directed to the references listed on the attached PTO/SB/08. It is respectfully requested that the information be expressly considered during the prosecution of this application, and that the references be made of record therein and appear among the "References Cited" on any patent to issue therefrom.

This Information Disclosure Statement is filed before the mailing date of a first Office Action on the merits as far as is known to the undersigned (37 CFR 1.97(b)(3)).

In accordance with 37 CFR 1.98(a)(2)(ii), Applicant has not submitted copies of U.S. patents and U.S. patent applications. Applicant submits herewith copies of foreign patents and non-patent literature in accordance with 37 CFR 1.98(a)(2).

In accordance with 37 CFR 1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made or that no other material information as defined in 37 CFR 1.56(a) exists. In accordance with 37 CFR

Application No.: 10/589,544 Docket No.: 27373/40386

1.97(h), the filing of this Information Disclosure Statement shall not be construed to be an admission that any patent, publication or other information referred to therein is "prior art" for this invention unless specifically designated as such.

It is submitted that the Information Disclosure Statement is in compliance with 37 CFR 1.98 and the Examiner is respectfully requested to consider the listed references.

The Director is hereby authorized to charge any deficiency in the fees filed, asserted to be filed or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Deposit Account No. 13-2855, under Order No. 27373/40386. A duplicate copy of this paper is enclosed.

Dated: May 29, 2007

Respectfully submitted,

William K. Merkel

Registration No.: 40,725

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PTO/SB/08A/B (09-06)

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Substitute for form 1449/PTO

Application Number 10/589 544

## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1 of 3

Complete if Known				
Application Number	10/589,544			
Filing Date	August 16, 2006			
First Named Inventor	Eugene B. Chang			
Art Unit	Not Yet Assigned			
Examiner Name	Not Yet Assigned			
Attorney Docket Number	27373/40386			

	U.S. PATENT DOCUMENTS				
Examiner Initials*	Cite No.1	Document Number  Number-Kind Code <sup>2</sup> ( <i>if known</i> )	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		6,096,711	08-01-2000	Sherman et al.	

	FOREIGN PATENT DOCUMENTS							
Examiner Initials*	Cite No.1	Foreign Patent Document  Country Code <sup>3</sup> -Number <sup>4</sup> -Kind Code <sup>5</sup> (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	   T⁰		

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		NON PATENT LITERATURE DOCUMENTS	
Examiner Initials	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
		Annuk et al., "Characterization of intestinal lactobacilli as putative probiotic candidates," J. Appl. Microbial., 94:403-412, 2003	
		Arvola et al., "Prophylactic Lactobacillus GG Reduces Antiobiotic-Associated Diarrhea in Children With Respiratory Infections: A Randomized Study," Pediatrics, 104(5):1-4, 1999	
		Beck, "Presence of the Stress-Inducible Form of hsp-70 (hsp-72) in Normal Rat Colon," Shock, 3:398-402, 1995	
		Besnard et al., "Postoperative outcome of Crohn's disease in 30 children," Gut, 43:634-638, 1998	
		Boone et al., "Recent Advances in Understanding NF-κB Regulation," Inflamm. Bowel Dis., 8:201-212, 2002	
		Braude et al., "The Influence of Bacteriocins on Resistance to Infection by Gram-Negative Bacteria," J. Clin. Invest., 47:1763-1773, 1968	
		Campierei et al., "Combination of antibiotic and probiotic treatment is efficacious in prophylaxis of post-operative recurrence of Crohn's disease: A randomized controlled study vs mesalamine," Gastroenterology, 118:A4179, 2000	
		Chang, In: "Intestinal Epithelial Function and Response to Mucosal Injury in Inflammatory Bowel Diseases," Inflammatory Bowel Diseases, Kirsner (Ed.), Philadelphia, W. BSaunders Company, 3-19, 1999	
		Cleveland et al., "Bacteriocins: safe, natural antimicrobials for food preservation," Int. J. Food Microbiol., 71:1-20, 2001	
		Gao, J. Clin., "Inhibition of ubiquitin-proteasome pathway-mediated IκBα degradation by a naturally occurring antibacterial peptide," Invest,. 106:439-448, 2000	
		Gionchetti et al., "Oral Bacteriotherapy as Maintenance Treatment in Patients With Chronic Pouchitis: A Double-Blind, Placebo-Controlled Trial," Gastroenterology, 119:305-309, 2000	
		Gionchetti et al., "Prophylaxis of Pouchitis Onset With Probiotic Therapy: A Double-Blind, Placebo-Controlled Trial," Gastroenterology, 124:1202-1209, 2003	

Examiner Date Signature Considered			
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Approved for use through 03/31/2007. OMB 0651-0031
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Sub	Substitute for form 1449/PTO			Complete if Known		
				Application Number	10/589,544	
IN	<b>IFORMATIO</b>	N DI	SCLOSURE	Filing Date	August 16, 2006	
S	STATEMENT BY APPLICANT			First Named Inventor	Eugene B. Chang	
				Art Unit	Not Yet Assigned	
	(Use as many s	heets as	s necessary)	Examiner Name	Not Yet Assigned	
Sheet	2	of	3	Attorney Docket Number	27373/40386	

Gionchetti et al., "Probiotics in infective diarrhoea and inflammatory bowel diseases," J. Gastroenterol. Hepatol., 15:489-493, 2000	
International Search Report from PCT/US05/03765	
Isolauri et al., "A Human Lactobacilus Strain (Lactobacillus Casei sp strain GG) Promotes Recovery From Acute Diarrhea in Children," Pediatrics, 88:90-97. 1991	
Jobin et al., "NF-kB Signaling Proteins as Therapeutic Targets for Inflammatory Bowel Diseases," Inflamm. Bowel Dis., 6:206-213, 2000	
Kisselev et al., "Proteasome inhibitors: from research tools to drug candidates," Chem. & Biol., 8:739-758, 2001	
Kojima et al., "Enteric Flora and Lymphocyte-Derived Cytokines Determine Expression of Heat Shock Proteins in Mouse Colonic Epithelial Cells," Gastroenterology, 124:1395-1407, 2003	
Kullisaar et al., "Two Antioxidative Lactobacilli Strains as Promising Probiotics," Int. J. Food Microbiol., 72:215-224, 2002	
Lee et al., "Proteasome Inhibitors Cause Induction of Heat Shock Proteins and Trehalose, Which Together Confer Thermotolerance in Saccharomyces cerevisiae," Mol. Cell. Biol., 18:30-38, 1998	
Lee et al., "Quantitative Approach in the Study of Adhesion of Lactic Acid Bacteria to Intestinal Cells and Their Competition with Enterobacteria," Appl. Environ. Microbiol., 66:3692-3697, 2000	
Lee et al., "Displacement of bacterial pathogens from mucus and Caco-2 cell surface by lactobacilli," J. Med. Microbiol., 52:925-930, 2003	
Leiper et al., "Adjuvant post-operative therapy," Baillieres Clin. Gastroenterol., 12(1):179-99, 1998	
Liu et al., "Protective role of HSP72 against Clostridium difficile toxin A-induced intestinal epithelial cell dysfunction," Am. J. Physiol Cell Physiol, 284:C1073-1082, 2003	
Maassen et al., "Strain-dependent induction of cytokine profiles in the gut by orally administered Lactobacillus strains," Vaccine, 18:2613-2623, 2000	
Madsen et al., "Probiotic Bacteria Enhance Murine and Human Intestinal Epithelial Barrier Function," Gastroenterology, 121:580-591, 2001	
Madsen, "Inflammatory bowel disease: lessons from the <i>IL-10</i> gene-deficient mouse," Clin Invest Med Vol. 24(5):250-257 (2001)	
Majamaa et al., "Lactic-Acid Bacteria in the Treatment of Acute Rotavirus Gastroenteritis," J. Pediatr. Gastroenterol. Nutr., 20:333-338, 1995	
Makowiec et al., "Long-term follow-up after resectional surgery in patients with Crohn's disease involving the colon," Z. Gastroenterol., 36(8):619-24, 1998	
Musch et al., "Induction of heat shock protein 70 protects intestinal epithelial IEC-18 cells from oxidant and thermal injury," Am. J. Physiol., 270:C429-436, 1996	
Musch et al., "Heat-Shock Protein 72 Protects Against Oxidant-Induced Injury of Barrier Function of Human Colonic Epithelial Caco2/bbe Cells," Gastroenterology, 117:115-122, 1999	
Myung et al., "The Ubiquitin-Proteasome Pathway and Proteasome Inhibitors," Med. Res. Rev., 21(4):245-273, 2001	
Neish, "Prokaryotic Regulation of Epithelial Responses by Inhibition of IκΒ-α Ubiquitination," Science, 289:1560-1563, 2000	
Neurath et al., "Cytokine Gene Transcription By NF-kB Family Members in Patients with Inflammatory Bowel Disease," Ann. NY Acad. Sci., 149-159, 1998	
Neurath et al., "Role of NF-kB in immune and inflammatory responses in the gut," Gut, 43:856-860, 1998	

Examiner	Date
Signature	Considered

PTO/SB/08A/B (09-06)
Approved for use through 03/31/2007. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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		_		Application Number	10/589,544	
IN	<b>IFORMATIO</b>	ON DIS	SCLOSURE	Filing Date	August 16, 2006	
S	TATEMEN1	ГВҮ А	PPLICANT	First Named Inventor	Eugene B. Chang	
				Art Unit	Not Yet Assigned	
	(Use as many	sheets as	necessary)	Examiner Name	Not Yet Assigned	
Sheet	3	of	3	Attorney Docket Number	27373/40386	

Neurath et al., "Local administration of antisense phosphorothioate oligonucleotides to the p65 subunit of NF-kB abrogates established experimental colitis in mice," Nat. Med., 2:998-1004, 1996	
Niedzielin et al., "A controlled, double-blind, randomized study on the efficacy of Lactobacillus plantarum 299V in patients with irritable bowel syndrome," Eur. Gastroenterol. Hepatol, 13:1143-1147, 2001	
Ocana et al., "Selection of Vaginal H <sub>2</sub> O <sub>2</sub> -Generating Lactobacillus Species for Probiotic Use," Curr. Microbiol., 38:279-284, 1999	
Paraje et al., "Conservation in Probiotic Preparations of Lactobacillus with Inhibitory Capacity on other Species," New Microbiol., 23:423-431, 2000	
Parsell and Lindquist, "The Function of Heat-Shock Proteins in Stress Tolerance: Degradation and Reactivation of Damaged Proteins," Annu. Rev. Genet., 27:437-496, 1993	
Pirkkala, "Disruption of Heat Shock Factor 1 Reveals an Essential Role in the Ubiquitin Proteolytic Pathway," Mal. Cell Biol., 20:2670-2675, 2000	
Podolsky, "Inflammatory Bowel Disease," N. Engl. J. Med., 347:417-429, 2002	
Remington's Pharmaceutical Sciences, 15th ed., pages 1035-1038 and 1570-1580, Mack Publishing Company, Easton, PA, 1980	
Ropeleski et al., "Interleukin-11-Induced Heat Shock Protein 25 Confers Intestinal Epithelial- Specific Cytoprotection From Oxidant Stress," Gastroenterology, 124:1358-1368, 2003	
Schmid et al., "NF-kB/Rel/lkB: Implications in Gastrointestinal Diseases," Gastroenterology, 118:1208-1228, 2000	
Schmitz et al., "Altered Tight Junction Structure Contributes to the Impaired Epithelial Barrier Function in Ulcerative Colitis," Gastroenterology, 116:301-309, 1999	
Smith et al., "Measurement of Protein Using Bicinchoninic Acid," Anal. Biochem., 150:76-85, 1985	
Urayama et al., "Dexamethasone Protection of Rat Intestinal Epithelial Cells against Oxidant Injury is Mediated by Induction of Heat Shock Protein 72," J. Clin. Invest., 102:1860-1865, 1998	
Voges, "The 26S Proteasome: A Molecular Machine Designed for Controlled Proteolysis," Annu. Rev. Biochem., 68:1015-1068, 1999	
Whitehead et al., "Establishment of conditionally immortalized epithelial cell lines from both colon and small intestine of adult H-2K <sup>b</sup> -tsA58," Proc. Natl. Acad. Sci. USA, 90:587-591, 1993	
Wollowski et al., "Protective role of probiotics and prebiotics in colon cancer <sup>1-3</sup> ," Amer. J. Clinical Nutrition, 73:451S-455S, 2001	

<sup>\*</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Examiner	Date
Signature	Considered

<sup>&</sup>lt;sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup>Applicant is to place a check mark here if English language Translation is attached.